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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,995	10/30/2003	Dorothea Reilly	146392005000	7395
25226 7590 10/08/2008 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018				
EXAMINER				
OUSPENSKI, ILIA I				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
10/08/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/697,995

**Applicant(s)**

REILLY ET AL.

**Examiner**

ILIA OUSPENSKI

**Art Unit**

1644

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 66 - 68, 70 - 76, 79 - 87, 90 - 101, 103 - 104, and 133 - 134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66 - 68, 70 - 76, 79 - 87, 90 - 101, 103 - 104, and 133 - 134 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. Applicant's amendment and remarks, filed on 06/26/2008, are acknowledged.

Claims 66 – 68, 70 – 76, 79 – 87, 90 – 101, 103 – 104, and 133 – 134 are pending.

Claims 86 and 100, previously withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions/Species, are presently rejoined and examined on the merits.

Therefore, claims 66 – 68, 70 – 76, 79 – 87, 90 – 101, 103 – 104, and 133 – 134 are presently under consideration.

The rejection of record has been withdrawn in view of Applicant's amendment and arguments.

New grounds of rejection, necessitated by Applicant's amendment, are set forth herein.

2. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

3. Claims 66 – 68, 70 – 76, 79 – 87, 90 – 101, 103 – 104, and 133 – 134 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 66 – 68, 70 – 76, 79 – 87, 90 – 101, 103 – 104, and 133 – 134 are indefinite in the recitation of “a nucleic acid comprising an antibody” in claim 66, clause (a), part (i), because an antibody is a polypeptide and it is unclear how a polypeptide can be comprised by a nucleic acid.

B. Claims 66 – 68, 70 – 76, 79 – 87, 90 – 101, 103 – 104, and 133 – 134 are indefinite because of an inconsistency between parts (i) and (ii) of clause (a) of claim 66, because part (i) recites a step of providing a nucleic acid [encoding] an antibody lacking a disulfide bond, while part (ii) recites a step of modifying the nucleic acid to lack a cysteine residue, which step implies that a non-modified nucleic acid is provided in step (i).

C. Claim 85 is indefinite in the recitation of “a single polynucleotide,” because the recitation lacks proper antecedent basis in the base claim.

D. Claims 93 – 95 are indefinite in the recitation of “the antibody,” because it is unclear which antibody is encompassed by the scope of the claim. Applicant is invited to consider amending the claims to recite “the corresponding antibody.”

E. Claims 133 and 134 are indefinite in the recitation of a “secretion signal sequence operably linked to the polynucleotide,” because a secretion signal sequence is a polypeptide and it is unclear whether a linkage between a polynucleotide and a polypeptide is encompassed by the claims.

Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

4. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

5. Claim 137 is rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant asserts that no New Matter has been added and points to the specification at page 37, lines 1 – 25 for support for the newly added claim 137. However, the specification does not appear to provide an adequate written description of the generic recitation of “a *Serratia* sp. Cell,” because it contains support only for the recitation of a single species *Serratia marcescans* at line 5 of page 37.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the

specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

**6. Conclusion: no claim is allowed.**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

October 7, 2008